



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,986	09/07/2006	Ryuji Ueno	Q80545	9326
23373 7590 02/03/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
THOMAS, TIMOTHY P				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
02/03/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/591,986

**Applicant(s)**

UENO ET AL.

**Examiner**

TIMOTHY P. THOMAS

**Art Unit**

1614

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 09 January 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 09 January 2009. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1 and 3-10.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). 6/20/2008  
13. ☐ Other: \_\_\_\_\_.

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

/Timothy P Thomas/  
Examiner, Art Unit 1614

Continuation of 11, does NOT place the application in condition for allowance because: The rejection of record is maintained for the reasons of record.

Applicants argue that the scope of the compound of the instant invention is quite different from Inoue. This is not persuasive because Inoue teaches the elected compound, as present in the record. Applicant further argues an inventive feature of the instant application is the deterioration of solubility by the presence of NaCl and that the deterioration is not a function of pH of the aqueous solution but the structure of the terminal group of the compound, according to Test Example 1. This is not persuasive because no such solubility properties are required by the instant claims. Applicant further argues that since Inoue suggests the use of NaCl as an isotonic agent in addition to glucose; therefore the art would not be motivated to chose an additive from the group of polyol, sugar alcohol, boric acid and a salt of boric acid. This is not persuasive; first, the instant claims do not excluded NaCl; secondly, the teaching of glucose, a sugar certainly would lead to the substitution for other related compounds such as a polyol or a sugar alcohol; third, the rejection is not based on Inoue alone, but on the combination of references.

Applicant argues other ionic components also lead to decreased solubility; the additives does not comprise any ionic component. This is not persuasive. Ionic compounds, although not specifically recited, are not excluded from the instant claims by the open language "comprising".

Applicant argues that the structure of the compound disclosed in Ogata is completely different from the instant invention, resulting in diminished solubility in water at pH 3-6.5; in contrast the compound of instant claim 1 is always decreased, irrespective of the pH; the conclusion argued is the the art would not come up with the idea to apply the isotonic agents for quinolone carboxylic acid for the compound of instant formula (I). This is not persuasive. The fact that Ogata teaches glycerin, mannitol, boric acid and glucose as isotonic agents would lead to their substitution in the Inoue compositions. According to MPEP 2144.06 (II), it would have been obvious to substitute an art recognized equivalent known for the same purpose (in the instant case as isotonic agents).

Applicant argues that since Inoue does not even suggest the object of the present invention, i.e., preparing a clear and stable aqueous composition with the specific compound of the instant invention whose solubility in water will be decreased in the presence of an ionic component this somehow renders the instant claims patentable over the cited art. This is not persuasive, because such language does not appear in the claims, nor are any concentrations recited in the claims.

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614